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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,639	10/08/2003	Qinwei Shi	12927-7 LAB	6090

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EXAMINER
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YU, MELANIE J

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/681,639

Applicant(s)

SHI, QINWEI

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,8,9,14-19,22,23 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,10-13,20,21,24-26 and 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/15,4/27,5/3

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Troponin I from group A and a notch on the bottom of the top surface from group B, in the reply filed on 25 October 2006 is acknowledged. The traversal is on the ground(s) that the different analyte listed in group A are merely examples of analytes that can be used in the invention and the different structures of group B do not result in different layers and merely provides alternative entry means for a sample. Applicant further argues that no separate searches or undue burden would be required. This is not found persuasive because each of the analytes listed requires the device to comprise biologically different reagents, and therefore requires separate searches. Furthermore, the different structures of group B require different searches because each requires the indent in a different portion of the device. Claims 3, 4, 8, 9, 14-19, 22, 23 and 27-32 have been withdrawn as being drawn to non-elected claims.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Objections***

2. Claims 2, 5, 7, 10-13, 21, 24-26 and 33-35 are objected to because of the following informalities: claims 2 and 5 recite "A platform according to claim 1" and should be changed to "The platform of claim 1 further comprising ...". Claims 7, 10-13, 21, 24-26 and 33-35 recite "A device according to claim 6(20)" and should be changed to "The method of claim 6(20) further comprising...". In line 16 of claim 20, the word "such" should be deleted for clarity. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1, 2, 5-7, 10-13, 20, 21, 24-26 and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a platform useful for containing", which is vague because it is unclear whether the platform is intended to contain the subsequent structural limitations of dry porous membranes and channels or whether the platform must merely be "capable of and useful for" containing the recited limitations. The claim should read "a platform comprising one or more...". It is also unclear whether the membrane channel is the same as the platform flow channel, and if the channels are not the same, it is unclear how they are related to one another. It is further vague as to whether "the membrane" recited in line 2, 6 and 9-11 are the same as the "one or more dry porous membranes" recited in line 1 of the claim.

With respect to claims 2, 7 and 21, it is unclear whether the claims are drawn to a device/platform or a method of making the device/platform. It is unclear whether the claim is reciting the method of forming the platform flow channel or whether the claim intends to encompass the structural limitation of a platform flow channel having an indent in the bottom surface of the top layer.

Claims 5, 10 and 24 fails to recite a transitional phrase of "comprising", "consisting of" or "consisting essentially of", and it is therefore unclear whether the claim intends to recite a platform comprising a window in the top layer.

Claims 6 and 20 recite "A device useful for..." and it is unclear whether the limitations are intended to be part of the device or whether the device must merely be capable of performing the recited limitations. It is unclear whether "the component" recited in line 5 of claim 20 is intended to be the same as the "one or more components" recite in line 1 of the claim. It is unclear whether "while they remain in the overlapping relationships" recited in

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lines 14-15 of claim 20 is the same as "the downstream end of the detection membrane slightly overlapping the upstream end of the capture membrane" of lines 9-10 of the claim because it is unclear whether more than one "overlapping relationship" is present. Lines 16-21 of claim 20 and lines 4-11 of claim 6 are vague because it is unclear whether the limitations are intended to encompass the method of placing the surfaces in face to face contact or whether the final physical structure is being claimed. The word "forming" should be changed to "form", the word "including" should be changed to "include" and the phrase "the formed channel being in communication" should be changed to "the formed channel is in communication".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Yu (US 6,723,500).

Kang et al. teach a device comprising one or more dry porous membranes, wherein the membranes provide a membrane channel through which the liquid sample can flow by capillary action while reactions take place to determine at least one component in the sample (col. 4, lines 47-38; col. 4, lines 50-65); wherein the platform is formed with sample application means, holds the membrane in place and forms a flow channel upstream of the membrane, the formed channel being in communication with the membrane to permit the liquid to flow in a continuous pathway from the sample application means to the distal end of the membrane (col. 4, lines 50-54). Kang et al. fail to teach the platform formed by face to face contact of a top and bottom layer having a bottom and top hydrophilic surface, respectively and an indent in at least one of the hydrophilic surfaces.

Catt et al. teach a test strip (204, Fig. 2) mounted in a plastic platform that has a top and bottom layer (top layer, 200, bottom layer, 201, Fig. 2; col. 23, lines 25-44) to enclose and position a membrane so that the bottom surface of the top layer and the top surface of the bottom layer are brought into fixed face to face contact to enclose the membrane in place and including an indent in the bottom surface of the top layer to form a channel to hold the membrane (Fig. 2; col. 23, lines 25-44), in order to provide a good moisture conducive junction between porous membranes. Catt et al. fail to specifically teach the plastic platform being hydrophilic.

Yu teaches a channel that is hydrophilic wherein a hydrophilic matrix may be placed inside the channel (one or more of the embodiments would include a hydrophilic channel wherein a hydrophilic matrix is within the channel, col. 11, lines 32-56), in order to provide sample flow through the channel.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al., a platform having a top and bottom layer that are placed in face to face contact to hold the membrane in place

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with an indent in the bottom surface of the top layer to form a channel as taught by Catt et al., in order to provide a test strip casing that is inexpensive to produce and easy to assemble. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al., the plastic platform surfaces forming the channel being hydrophilic as taught by Yu, in order to provide an accurate, precise and efficient test strip wherein sample is moved quickly through a channel.

With respect to claims 5, 10 and 24, Kang et al. teach a window in the top of the device for observing the results of a reaction which takes place in the membrane (col. 4, lines 50-56) and Catt et al. teach a window in the top layer of the device (col. 23, lines 34-39).

Regarding claims 11 and 25, Kang et al. teach that a plurality of reagents may be present for detecting one or more analyte (col. 5, lines 1-11).

With respect to claim 20, Kang et al. teach the device containing an upstream detection membrane and a downstream capture membrane (filter elements and wicking membrane, col. 4, lines 20-38; col. 3, lines 50-61), wherein the detection membrane constructed to filter unwanted components from the sample and containing a mobile labeled detection region which will react with the component to form a reaction product which moves downstream in the detection membrane (although Kang does not specifically teach removing red blood cells, the filter is capable of removing red blood cells if the cells are the unwanted components, col. 3, lines 24-42); a capture membrane downstream of the detection membrane and containing a fixed, immobile capture reagent which will react with and concentrate the reaction product at a capture line (col. 3, lines 50-60), the downstream end of the detection membrane slightly overlapping the upstream end of the capture membrane (col. 5, lines 45-53); the membranes being enclosed in a platform (described

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above in the explanation of obviousness over Kang et al. in view of Catt et al. further in view of Yu) wherein the sample flows in a continuous path from the application means through the detection membrane to the distal end of the capture membrane (col. 4, lines 50-65).

Regarding claim 33, Kang et al. teach the detection membrane being a glass fiber membrane (col. 6, lines 32-35) and the capture membrane being a nitrocellulose membrane (wicking membrane, col. 6, lines 38-42).

With respect to claim 34, Kang et al. teach the membranes covered with a transparent cover layer (col. 7, lines 23-25).

Regarding claim 35, Catt et al. teach the porous material sandwiched between two transparent layers of polyester film (col. 25, line 63-col. 26, line 5).

5. Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141).

Kang et al. teach a device comprising one or more dry porous membranes, wherein the membranes provide a membrane channel through which the liquid sample can flow by capillary action while reactions take place to determine at least one component in the sample (col. 4, lines 47-38; col. 4, lines 50-65); wherein the platform is formed with sample application means, holds the membrane in place and forms a flow channel upstream of the membrane, the formed channel being in communication with the membrane to permit the liquid to flow in a continuous pathway from the sample application means to the distal end of the membrane (col. 4, lines 50-54). Kang et al. fail to teach the platform formed by face to face contact of a top and bottom layer having a bottom and top hydrophilic surface, respectively and an indent in at least one of the hydrophilic surfaces.



Catt et al. teach a test strip (204, Fig. 2) mounted in a plastic platform that has a top and bottom layer (top layer, 200, bottom layer, 201, Fig. 2; col. 23, lines 25-44) to enclose and position a membrane so that the bottom surface of the top layer and the top surface of the bottom layer are brought into fixed face to face contact to enclose the membrane in place and including an indent in the bottom surface of the top layer to form a channel to hold the membrane (Fig. 2; col. 23, lines 25-44), in order to provide a good moisture conductive junction between porous membranes. Catt et al. fail to specifically teach the plastic platform being hydrophilic.

Segal et al. teach a channel comprising a hydrophilic porous material (col. 13, lines 21-25; col. 12, lines 23-40) wherein the channel is made out of the substrate material which is a non-porous rigid, moisture impermeable material of either polystyrene or glass (col. 9, lines 6-21), in order to provide sample flow through the channel.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al., a platform having a top and bottom layer that are placed in face to face contact to hold the membrane in place with an indent in the bottom surface of the top layer to form a channel as taught by Catt et al., in order to provide a test strip casing that is inexpensive to produce and easy to assemble. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al., the platform surfaces forming the channel being glass, which is a hydrophilic material as taught by Segal et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent substrate material and since the same fluid transport and device structure would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the *economics and availability of components*.

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With respect to claims 5, 10 and 24, Kang et al. teach a window in the top of the device for observing the results of a reaction which takes place in the membrane (col. 4, lines 50-56) and Catt et al. teach a window in the top layer of the device (col. 23, lines 34-39).

Regarding claims 11 and 25, Kang et al. teach that a plurality of reagents may be present for detecting one or more analyte (col. 5, lines 1-11).

With respect to claim 20, Kang et al. teach the device containing an upstream detection membrane and a downstream capture membrane (filter elements and wicking membrane, col. 4, lines 20-38; col. 3, lines 50-61), wherein the detection membrane constructed to filter unwanted components from the sample and containing a mobile labeled detection region which will react with the component to form a reaction product which moves downstream in the detection membrane (although Kang does not specifically teach removing red blood cells, the filter is capable of removing red blood cells if the cells are the unwanted components, col. 3, lines 24-42); a capture membrane downstream of the detection membrane and containing a fixed, immobile capture reagent which will react with and concentrate the reaction product at a capture line (col. 3, lines 50-60), the downstream end of the detection membrane slightly overlapping the upstream end of the capture membrane (col. 5, lines 45-53); the membranes being enclosed in a platform (described above in the explanation of obviousness over Kang et al. in view of Catt et al. further in view of Segal et al.) wherein the sample flows in a continuous path from the application means through the detection membrane to the distal end of the capture membrane (col. 4, lines 50-65).

Regarding claim 33, Kang et al. teach the detection membrane being a glass fiber membrane (col. 6, lines 32-35) and the capture membrane being a nitrocellulose membrane (wicking membrane, col. 6, lines 38-42).

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With respect to claim 34, Kang et al. teach the membranes covered with a transparent cover layer (col. 7, lines 23-25).

Regarding claim 35, Catt et al. teach the porous material sandwiched between two transparent layers of polyester film (col. 25, line 63-col. 26, line 5).

6. Claims 12, 13 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141), as applied to claims 6 and 20, and Freitag et al. (US 6,214,629).

Kang et al. in view of Catt et al. further in view of Segal et al. teach a device comprising reagents for analyte detection, but fail to teach the analyte being Troponin I.

Freitag et al. teach reagents for the detection of Troponin I in a chromatographic assay (col. 9, line 63-col. 10, line 21), in order to provide detection of cardiac analytes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Kang et al. in view of Catt et al. further in view of Segal et al., reagents in a porous material for the detection of Troponin I in a blood sample as taught by Freitag et al., in order to provide diagnosis for the cause of chest pain and to determine a cardiac event.

### ***Conclusion***

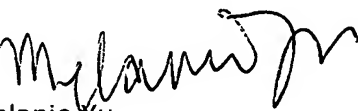
No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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Art Unit 1641

  
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